

Application No. 10/687,289
Response dated May 24, 2006
Response to Office Action dated February 24, 2006

REMARKS/ARGUMENTS

The Office Action of February 24, 2006 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1 - 37 remain pending in the application. Claims 1-19 and 20-37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pub. No. 2002/0013612 to Whitehurst (Whitehurst). Claims 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitehurst in view of U.S. Pub. No. 2002/0013613 to Haller *et al.* (Haller). In response, Applicants respectfully traverse the rejections in view of the remarks provided below.

Rejection under 35 U.S.C. §102 - Whitehurst

Claims 1-19 and 20-37 were rejected under 35 U.S.C. § 102(e) in as being anticipated by Whitehurst. Claims 1, 11, 13 and 37 are independent.

Independent claim 1 recites the feature of "wherein the implantable component is configured to operate with the first treatment therapy mode when the external component is decoupled from the communications channel and to operate with the second treatment therapy mode when the external component is coupled to the communications channel." Applicants first note that Whitehurst does not expressly mention switching between modes depending on whether an external device is in communication with a SCU 130. Therefore, it appears that the Office Action is suggesting that the above recited feature is inherent in the operation of Whitehurst. Applicants further note that for something to be inherent, the feature that is argued to be inherent must necessarily be present in the cited reference. The Office Action points to paragraph 90 of the Whitehurst as disclosing switching between a first and a second mode. Paragraph 90 is provided below:

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[0090] While an SCU 130 may also incorporate means of sensing symptoms or other prognostic or diagnostic indicators of mood and/or anxiety disorders, e.g., via levels of a neurotransmitter or hormone, it may alternatively or additionally be desirable to use a separate or specialized implantable device to record and telemeter physiological conditions/responses in order to adjust electrical stimulation and/or drug infusion parameters. This information may be transmitted to an external device, such as external appliance 220, or may be transmitted directly to implanted SCU(s) 130. However, in some cases, it may not be necessary or desired to include a sensing function or device, in which case

stimulation parameters are determined and refined, for instance, by patient feedback.

Whitehurst, pg. 8, ¶ 90. Applicants respectfully submit that this paragraph, as well as the rest of Whitehurst, does not support the Office Action's reasoning.

Paragraph 90 of Whitehurst, and Whitehurst in general, indicates that the SCU 130 may include a sensing means in a first configuration that would support a closed loop configuration, thus a first configuration would include a sensor and be closed loop and a second configuration would be open loop without a sensor. A third configuration may include a separate implantable device to record and telemeter data either to the SCU 130 or to an external device. Therefore, Whitehurst, when read fairly, at most suggests that the SCU 130 could be operated in either closed loop or open loop configuration, with or without a separate implantable device that is configured to telemeter data to either the SCU 130 or the external device.

However, Whitehurst fails to disclose that the SCU 130 may, for example, first function in one mode and then function in a second mode when external device is in communication with the SCU 130. Indeed, Applicants have been unable to locate any disclosure in Whitehurst that suggests the SCU 130 will change modes because of the proximity of an external device. Nor is there any disclosure that the SCU 130 reverts back to a different mode once the external device is no longer in communication with the SCU 130. Instead, the discussion about the use of external devices in conjunction with the SCU 130 is related to programming or recharging the SCU 130. In addition, the ability to switch between modes when an external device is present is not inherent in Whitehurst because plainly it is possible for Whitehurst to function in a single

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mode, such as open loop electrical stimulation, regardless of the presence of the external device. Applicants respectfully submit that the concept of switching between modes in response to the presence of an external device in communication with the SCU 130 is simply not contemplated by Whitehurst. Applicants further respectfully submit that the Office Action's reading of Whitehurst can only be supported by using the teaching of the present application to inform and modify Whitehurst.

The Office Action suggests that paragraph 90 discloses that the SCU 130 is initially in a closed-loop mode but the presence of an external device causes the SCU 130 to switch to an open-loop mode. However, paragraph 90 merely says that if a separate implanted device is being used, it may telemeter data to the SCU 130 or the external device. There is no mention in paragraph 90 of changing the destination of the data in response to bringing an external device in communication with the SCU 130. Thus, paragraph 90 of Whitehurst does not support the Office Action's reasoning and simply does not disclose such a feature.

In addition, the Office Action's reading of Whitehurst does not appear to be logical – Applicants cannot envision a reason supported by the disclosure in Whitehurst for switching from closed loop treatment to open-loop treatment when the external device is in communication with the implanted device. If the SCU 130 was configured to provide closed loop treatment, there is nothing in paragraph 90 of Whitehurst that suggest that presence of the external device would change this. Instead, Whitehurst merely discloses that a separate implanted device may telemeter data to the external device. Thus, a fair reading of Whitehurst is that if the SCU 130 is operating in closed loop mode, the presence of an external device would allow the operator to see if the treatment was being successful, and if the current settings were not what was desired, the operator could adjust the parameters of the closed loop stimulation so that future treatment would be more successful. However, the SCU 130 would still be operating in closed loop treatment during this time and the presence or absence of the external device would not affect this operational mode.

Accordingly, for at least the above reasons, Whitehurst fails to disclose all the features of claim 1 and therefore cannot be said to anticipate claim 1.

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Independent claims 11 and 13 recite similar features and therefore, are not anticipated for at least the reasons discussed above with respect to independent claim 1 and for the additional features recited therein.

Claims 2-10, 12, 14-19 and 21-36 depend from the above reference independent claims 1, 11, and 13 and are not anticipated for at least the reasons discussed above and for the additional features recited therein.

Independent claim 37 recites the features of "if the external component and the implantable component are coupled, supporting a closed-loop mode with the external component in accordance with the neurological data; and... if the external component and the implantable component are decoupled, continuing to operate the medical device system with the open-loop mode of the treatment therapy." Even under the reasoning used by the Office Action, which as discussed above, is not supported by Whitehurst, claim 37 recites a method that is the opposite of what the Office Action suggests that Whitehurst discloses. Therefore, in addition to the reasons discussed above with respect to claim 1, Whitehurst cannot be said to disclose all the features of claim 37 for this additional reason.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claim 20 was rejected under 35 USC §103(a) as being unpatentable over Whitehurst in view of Haller. The Office Action did not suggest, however, that Haller could correct the above noted deficiencies in Whitehurst, nor does Haller appear so capable. Therefore, the combination of Whitehurst and Haller fails to disclose all the features of claim 20 for at least the reasons discussed above with respect to independent claim 13 and for the additional features recited therein. As Whitehurst and Haller fail to disclose all the features of claim 20, Whitehurst and Haller fail to support a *prima facie* case of obviousness with respect to claim 20 and therefore, claim 20 is patentable over the combination of Whitehurst and Haller.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

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CONCLUSION

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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